MQSA FACILITY CERTIFICATION REQUIREMENTS
FOR USE OF
FULL FIELD DIGITAL MAMMOGRAPHY (FFDM)

1. Facility Status Information
   a. Facility Name and FDA Facility ID Number
   b. FDA Certificate Expiration Date
   c. Current Accreditation Body for Screen-Film Unit(s)
   d. Accreditation Expiration Date
   e. Facility Contact Person for FFDM (if different from screen-film contact)
   f. Contact Person's Title
   g. Contact Person's Telephone, Fax, E-mail
   h. Facility Address
   i. Facility Owner

2. FFDM Unit Identification
   a. Machine Manufacturer
   b. Machine Model
   c. Year of Manufacture
   d. Serial Number

3. Digital Image Receptor Identification (if interchangeable)
   a. Receptor Manufacturer
   b. Receptor Model
   c. Year of Manufacture
   d. Serial Number (if applicable)

4. Identification of Printer for Hard Copy Output
   a. Printer Manufacturer
   b. Printer Model
   c. Year of Manufacture
   d. Serial Number

5. Monitor Identification (if soft copy display is available)
   a. Monitor Manufacturer
   b. Monitor Model
   c. Year of Manufacture
   d. Serial Number

6. Phantom Identification
   a. Phantom Manufacturer
   b. Phantom Model

7. **Personnel Qualifications**
   a. Interpreting Physicians who are qualified to interpret hard and soft copy digital mammograms (See page 4)
   b. Radiological Technologists who are qualified to perform digital mammography examinations and the manufacturer recommended quality assurance tests (See page 5)
   c. Medical Physicists who are qualified to perform equipment evaluations and/or surveys of digital mammography units including tests of the Soft Copy Display system (See page 6)

8. **Report of Mammography Equipment Evaluation (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to the receipt of this letter)**
   a. Statement that equipment performance, as required under the following sections of the MQSA final regulation **21 CFR 900.12(b)**, is met:
      (1) Prohibited Equipment
      (2) Specifically Designed for Mammography
      (3) Motion of Tube-Image Receptor Assembly
      (4)(iii) Removable Grid (if applicable to the FFDM system used)
      (5) Beam Limitation and Light Fields
      (6) Magnification
      (7) Focal Spot Selection
      (8) Compression
      (9) Technique Factor Selection and Display (GE system may use AOP instead of AEC in this requirement)
      (10) Automatic Exposure Control (GE system may use AOP instead of AEC in this requirement)
      (14) Lighting (if hard copy display is used for image evaluation)
      (15) Film Masking Devices (if hard copy display is used for image evaluation)
   b. The results of quality control tests as required under the following sections of the MQSA final regulations **21CFR 900.12(e)**:
      (4)(iii) Compression Device Performance
      (5)(i) Automatic Exposure Control Performance (if applicable to the FFDM system used)
      (5)(ii) Kilovoltage Peak Accuracy and Reproducibility
      (5)(iii) Focal Spot Condition
      (5)(iv) Beam Quality and Half-Value Layer
      (5)(v) Breast Entrance Air Kerma and AEC Reproducibility (if applicable to the FFDM system used)
      (5)(vi) Dosimetry
      (5)(vii) X-Ray Field/Light field/Image receptor/Compression paddle alignment

[continued on next page]

(5)(ix) System Artifacts
(5)(x) Radiation Output
(5)(xi) Decompression (or alternative standards allowed for these requirements)
(6) Quality Control Tests – Other Modalities (Facilities must perform all FFDM manufacturer recommended quality control tests including the medical physicist's tests **for Soft Copy Display system**)

c. The results of the phantom image quality tests, including a sample image
d. If any of the requirements in 8 a, b, or c are not met, submit documentation of successful corrective action
e. If any of the requirements in 8 a or b are not performed, explain why the requirement is not applicable
f. Date of the evaluation
g. Name and address of the physicist(s) who performed the evaluation

9. Manufacturer's Quality Control Program

a. Name of the Quality Control Manual
b. Year published
c. Revision number, if not the original
d. Printing number, if not the original

10. Signature (see page 7)

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DIGITAL MAMMOGRAMS

List the current interpreting physicians who:

(1) meet all the requirements of CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *****; **AND**
(2) began interpreting digital mammograms **prior** to April 28, 1999.

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List the current interpreting physicians who:

(1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *****;
(2) began interpreting digital mammograms **after** April 28, 1999; **AND**
(3) have 8 hours of initial training in Full Field Digital Mammography*****.

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* **Supporting documentation for these requirements will be checked during annual MQSA inspections.**

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DIGITAL MAMMOGRAMS

List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *****; **AND**
(2) began performing digital mammography examinations **prior** to April 28, 1999.

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List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *****;
(2) began performing digital mammography examinations **after** April 28, 1999; **AND**
(3) have 8 hours of initial training in Full Field Digital Mammography*****.

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***Supporting documentation for these requirements will be checked during annual MQSA inspections.**

PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM FFDM SURVEYS

List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *****; **AND**

(2) began performing equipment evaluations and/or surveys of digital mammography units **prior** to April 28, 1999

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List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *****;

(3) began performing equipment evaluations and/or surveys of digital mammography units **after** April 28, 1999; **AND**

(3) have 8 hours of initial training in Full Field Digital Mammography*****.

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***** **Supporting documentation for these requirements will be checked during annual MQSA inspections.**

To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document.

I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.

Signature (Lead Interpreting Physician) _____

Print Name_____

Date_____